

DETAILED ACTION

Election/Restrictions

Claims 2-3, 10, 13-29, 76-77 and 83-106 are allowable. The species requirement of a disease and benzimidazole derivative, as set forth in the Office action mailed on 6/28/2004, has been reconsidered in view of the allowability of claims to the elected invention pursuant to MPEP § 821.04(a). **The species requirement is hereby withdrawn as to any claim that requires all the limitations of an allowable claim.** Claims 4-8, 11, and 78-82 are directed to the species which are no longer withdrawn from consideration because the claim(s) requires all the limitations of an allowable claim.

In view of the above noted withdrawal of the restriction requirement, applicant is advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application.

Once a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

This application is in condition for allowance except for the presence of claims 30-63, 65-74, 107-160, 163, 166, 168 and 171-175 are directed to patentably distinct inventions non-elected without traverse. Accordingly, claims 30-63, 65-74, 107-160, 163, 166, 168 and 171-175 have been cancelled.

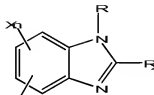
REASONS FOR ALLOWANCE

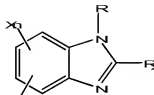
The following is an examiner's statement of reasons for allowance:

The rejection of claims 76-77, 83-97, 99-106 under 35 U.S.C. 103(a) as being unpatentable over Camden (US 6,262,093, 1999) in view of Perdoma *et al.* (J. Cancer Res. Clin. Oncol. 1998, 124, 10-18) in further view of Delatour *et al.* (IDS, Therapie 1976; 31 (4); 505-515) is withdrawn in view of the Declaration under 37 CFR 1.131 submitted on 4/28/2006 which established that Applicants were diligent from the conception of the present invention prior to March 9, 1999, the priority date

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of Camden I, up to the time of the priority date of the instant application, which was January 11, 2001. In the instant case, as noted by Applicants (page 9 of the Appeal Brief filed on 12/08/2006), Claim 12 of Camden I and Claim 1 from which it depends recites: A method of treating cancer selected from the group consisting of carcinoma, sarcoma, and lymphoma, the method comprising administering to a patient in need thereof a therapeutically effective amount of a composition



comprising a benzimidazole compound of the formula:  wherein, X is hydrogen, halogen, alkyl of less than 7 carbon atoms, or alkoxy of less than 7 carbon atoms; n is a positive integer of less than 4; Y is hydrogen, chloro, nitro, methyl, ethyl, or oxychloro; R is hydrogen, an alkyl group of from 1 to 8 carbon atoms, or alkylaminocarbonyl wherein the alkyl group has from 3 to 6 carbon atoms; and R_{sub.2} is HCOOR_{sub.1}, wherein R_{sub.1} is an aliphatic hydrocarbon of less than 7 carbon atoms; or a prodrug thereof, a pharmaceutically acceptable salt thereof, or mixtures thereof; and claim 12. A method of treating cancer according to claim 1, wherein the benzimidazole compound induces apoptosis in cancer cells at sub-lethal concentrations to normal cells. Claim 22 of the Present Invention recites: A method of inducing apoptosis in a tumor cell expressing a tumor suppressor gene comprising the steps of: (1) determining the tumor suppressor gene status of the tumor cell; and (2) administering an effective amount of a benzimidazole to said tumor cell, wherein expression of the tumor suppressor gene by the tumor cell and benzimidazole results in the apoptosis of the tumor cell. Claim 100 of the Present Invention recites: A method for treating a patient having cancer wherein the cancer cell expresses a tumor suppressor comprising the steps of: (1) determining the tumor suppressor gene status of the cancer cell; and (2) administering an effective amount of a benzimidazole to said patient, wherein the expression of the tumor suppressor gene by the cancer cell and the administration of the benzimidazole results in the inhibition of said cancer. Thus, while the subject matter of the claims of the present invention, if prior art, would have anticipated the subject matter of the claim in Camden I, the subject matter of the claim in Camden I does not anticipate the claims of the present invention or render the claims of the present invention obvious. In particular, the prior art does not appear to teach or suggest a nexus between benzimidazole and determining the tumor suppressor

gene status. As such, the Declaration under 37 CFR 1.131 submitted on 4/28/2006 was found sufficient to establish that Applicants were diligent from the conception of the present invention prior to March 9, 1999, the priority date of Camden I, up to the time of the priority date of the instant application, which was January 11, 2001.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BRANDON J. FETTEROLF whose telephone number is (571)272-2919. The examiner can normally be reached on Monday through Friday from 7:30 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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